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EXAMINER

KRASS, FREDERICK F

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 11/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/715,917	Applicant(s) MONTGOMERY, R. ERIC	
	Examiner Frederick F. Krass	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-53 and 59-79 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 28-42, 45 and 59-72 is/are allowed.
- 6) ☒ Claim(s) 43, 44, 46, 47, 49-53 and 73-79 is/are rejected.
- 7) ☒ Claim(s) 48 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

Written Description Rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 47 and 49-53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The following precedent is believed relevant to the instant case.

Regents of the University of California v. Eli Lilly & Co., 119 F.3d 1559, 1568 (Fed.Cir.1997), *cert. denied*, 523 U.S. 1089, 118 S.Ct. 1548 (1998), holds that an adequate written description requires a precise definition, such as by structure, formula, chemical name, or physical properties, "not a mere wish or plan for obtaining the claimed chemical invention." Eli Lilly, 119 F.3d at 1566. The Federal Circuit has adopted the standard set forth in the Patent and Trademark Office ("PTO") Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement ("Guidelines"), 66 Fed.Reg. 1099 (Jan. 5, 2001), which state that the written description requirement can be met by "showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics," including, *inter alia*, "functional characteristics when coupled with a known or disclosed correlation between function and structure" Enzo Biochem, Inc. v. Gen-Probe Inc., 296 F.3d, 316, 1324-25 (Fed. Cir. 2002) (quoting Guidelines, 66 Fed.Reg. at 1106 (emphasis added)). Moreover, although Eli Lilly and Enzo were decided within the factual context of DNA sequences, this does not preclude extending the reasoning of those cases to chemical structures in general. Univ. of Rochester v. G.D. Searle & Co., 249 F. Supp.2d 216, 225 (W.D.N.Y. 2003).

Art Unit: 1614

Applying the reasoning of the above-cited case law to the facts at hand, the instant specification fails to provide an adequate written description of suitable "sources" of "labile" acetyl groups. The specification describes only a limited number of suitable sources, namely C₁-C₃ molecules having 1 to 5 labile C₁-C₅ groups, as exemplified by glyceryl triacetate, glyceryl diacetate and glyceryl acetate. See page 11, lines 7 et seq. of the specification. No other detailed, relevant identifying characteristics are specified which would adequately describe other useful "sources" of "labile" acetyl groups. Indeed, these particular species are recognized to have very specific and unexpected characteristics rendering them suitable for use in tooth whitening compositions: see for example page 6, lines 3-9, page 7, lines 4-6, page 12, lines 10-20, and page 24, lines 16-24, for example. Applicant's disclosure that species other than C₁-C₃ molecules having 1 to 5 labile C₁-C₅ groups, as exemplified by glyceryl triacetate, glyceryl diacetate and glyceryl acetate, could be used is a "mere wish or plan" that other such molecules might exist; the simple fact is that no other species are actually disclosed, taught or even vaguely suggested.

Indefiniteness Rejection

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 49 and 73-79 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

i) Claim 49, the meaning of the "loss" is unclear (is this simply a typographical error, or is some unspecified "loss" actually being recited?)

ii) The term "substantially" in claim 73 is a relative term which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard

Art Unit: 1614

for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. In point of fact, the second component will either contain a source of hydrogen peroxide or it will not; there is no issue of possible trace amounts at question here.

Anticipation Rejection

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1) Claim 43 is rejected under 35 U.S.C. 102(e) as being anticipated by Michael et al (USP 5,885,554).

Patentees disclose compositions comprising triacetin (a.k.a. glyceryl triacetate) and aqueous hydrogen peroxide. See col. 2, line 64, col. 7, lines 23-27, and working example V at col. 10. Note that the working example prepares a composition containing triacetin, and then later adds the peroxide thereto (col. 10, lines 66 and 67). Before the peroxide is actually added, the composition would exist as two components. Furthermore, the limitation of the instant claims that the composition be “for producing peroxyacetic acid for use in whitening teeth” is merely a statement of intended use and would be anticipated by the prior art, whose compositions have the capability to do so, whether the prior art actually recognized that or not.

Art Unit: 1614

2) Claim 43 is rejected under 35 U.S.C. 102(b) as being anticipated by Nakagawa et al (USP 3,901,819).

Patentees disclose bleaching compositions comprising triacetin and aqueous hydrogen peroxide. See col. 2, line 13 and col. 2, lines 45-52, and working example I. Note that the working example prepares a composition containing peroxide, and then later adds the triacetin thereto (col. 3, lines 1-3). Before the triacetin is actually added, the composition would exist as two components. Furthermore, the limitation of the instant claims that the composition be "for producing peroxyacetic acid for use in whitening teeth" is merely a statement of intended use and would be anticipated by the prior art, whose compositions have the capability to do so, whether the prior art actually recognized same or not.

Obviousness Rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1) Claims 43, 44 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Church et al (USP 5,279,816) in view of Nakagawa et al (USP 3,901,819).

Art Unit: 1614

The primary reference discloses compositions for tooth whitening comprising peroxyacetic acid, which is generated in situ from a precursor having labile acetyl groups, such as sorbitol hexaacetate. See col. 3, lines 20-24 and working examples VI and VII at the last page of the patent. The primary reference differs from the instant claims insofar as it is silent regarding the use of glyceryl triacetate (a.k.a. triacetin).

The secondary reference discloses bleaching compositions containing activators comprising acetic acid esters of saccharides such as sorbitol hexaacetate. See col. 1, lines 44-67 and Table 2 at col. 3. The bleaching activity of these esters is increased by adding an acetic acid ester of a polyhydric alcohol, e.g. triacetin, thereto. See col. 2, lines 12-16 and working example 1. The secondary reference differs from the instant claims insofar as it does not specify the bleaching of teeth (instead it teaches bleaching applications generally, as illustrated by the bleaching of fabrics).

It would have been obvious to have added glyceryl triacetate to the tooth bleaching compositions of the primary reference, motivated by the desire to provide increased bleaching activity as taught by the secondary reference. The determination of suitable conditions, e.g. pH as required by instant claim 44, would have been obvious based on the natural desire of scientists to optimize performance. See for example In re Peterson, 315 F.3d 1325 (C.A. Fed 2003).

2) Claims 73-75, 78 and 79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Church et al (USP 5,279,816) in view of Nakagawa et al (USP 3,901,819), further in view of Pellico (USP 5,928,628).

The primary and secondary references, and the rationale for combining their teachings, is provided above. The combination differs from the instant claims insofar as both references are silent regarding use of a multi-chamber vessel, and more specifically one containing a single exit and a mixer (e.g. a dual compartment syringe).

The tertiary reference teaches that it is well-known in the tooth bleaching art to administer tooth bleaching compositions via a dual compartment syringe in which the peroxide component is contained in one chamber and the activator in the other. The advantage of doing so resides in the

Art Unit: 1614

increased bleaching activity which results from keeping the active ingredients from prematurely reacting until just before they are applied to the tooth. See for example the discussion of col. 2, lines 9-38 and the passage spanning col. 6, line 54 to col. 7, line 7. The tertiary reference differs from the instant claims insofar as it is silent regarding the use of an accelerator having labile acetyl groups, such as triacetin.

It would have been obvious to have administered the tooth bleaching compositions suggested by the combined teachings of the primary and secondary references with a dual compartment syringe, motivated by the desire to further increase bleaching activity as taught by the tertiary reference.

Obviousness-Type Double Patenting Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 44 and 46 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 6,221,341.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the conflicting claims recite certain specific application variables, e.g. percentage of components and pH. The determination of such particular conditions, however, would have been obvious based on the natural desire of scientists to optimize performance. It is well-settled that changes in application variables are normally not patentable where the difference involved is one of degree, not kind, because experimentation to find workable conditions

Art Unit: 1614

generally involves the application of no more than routine skill in the art. In re Aller 105 U.S.P.Q. 233.

Allowable Subject Matter

Claims 28-42, 45 and 59-72 are allowable as presently advised.

Claims 47-53 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112 set forth in this Office action.

Claim 48 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 76 and 77 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112 set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

The prior art of record does not fairly suggest, teach or disclose anhydrous tooth bleaching compositions comprising an activator having labile acetyl groups, such as glyceryl triacetate, and a peroxide source. The prior art, considered in its entirety, in fact teaches away from such compositions; each and every reference applied in the rejections supra does in fact require water as an integral component.

The prior art of record also does not fairly suggest, teach or disclose first administering to the tooth surface a peroxide or accelerator having labile acetyl groups, then administering the corresponding accelerator or peroxide to activate the component already present on the tooth surface.

Art Unit: 1614

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick F. Krass whose telephone number is 571-272-0580. The examiner's schedule is as follows:

Monday: 10:30AM- 7PM;
Tuesday: 10:30AM - 7PM;
Wednesday: off;
Thursday: 10:30AM- 7PM; and
Friday: 10:30AM-7PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass
Primary Examiner
Art Unit 1614

